



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 3, 2015

ROCHE DIAGNOSTICS
KHONE SAYSANA
PRINCIPLE REGULATORY AFFAIRS, DIABETES CARE
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K141867

Trade/Device Name: ACCU-CHEK® Aviva Connect Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: February 2, 2015
Received: February 3, 2015

Dear Khone Saysana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Stayce Beck -S

FOR : Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)
K141867

Device Name
ACCU-CHEK Aviva Connect Blood Glucose Monitoring System

Indications for Use (Describe)

The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Connect Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

For in vitro diagnostic use

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, Contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7593
Contact Person: Khone Saysana
Date Prepared: February 6, 2015

Device Name

Proprietary name:
ACCU-CHEK® Aviva Connect Blood Glucose Monitoring System

Meter: ACCU-CHEK Aviva Connect Meter
Test Strip: ACCU-CHEK Aviva Plus Test Strip
Controls: ACCU-CHEK Aviva Control Solutions

Classification name: Glucose dehydrogenase, glucose test system
(21 C.F.R. § 862.1345); Class II

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase

Predicate Device

ACCU-CHEK Aviva Plus System (K133862), concurrence received on 30 April 2014.

Device Description

The ACCU-CHEK Aviva Connect blood glucose monitoring system is a blood glucose monitoring system that makes use of the ACCU-CHEK Aviva Connect meter, the ACCU-CHEK Aviva Plus test strips (k101299), and the ACCU-CHEK Aviva control solutions (k101299). The ACCU-CHEK Aviva Connect meter is a modification of the ACCU-CHEK Aviva meter (k133862) with an improved design and the addition of a USB port and the BLE communication capability.

**Summary of
Technological
Characteristics
Compared to
the Predicate
Device**

System Feature	ACCU-CHEK Aviva Plus System (k133862, predicate)	ACCU-CHEK Aviva Connect System (new device)
Indications for Use	<p>The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.</p> <p>The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.</p> <p>The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Plus Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.</p>	Same
Meter Communication	Infrared Communication via dongle	USB (Universal Serial Bus) and BLE (Blue Tooth Low Energy) Communications
AST Claims	Palm, Upper Arm and Forearm	None
Meter Buttons	Arrow buttons on the front are used to toggle through memory	Button functionality has changed
Embedded PC Reports	No	Embedded Reports available for transmission to a Personal Computer
Meter Housing	Black housing	Modified black housing
Test Strip	Utilizes the ACCU-CHEK Aviva Plus test strip	Same
Meter Coding	Universal code or blood glucose measurement parameters are programmed into an internal EEPROM	Same

**Summary of
Technological
Characteristics
Compared to
the Predicate
Device**

System Feature	ACCU-CHEK Aviva Plus System (k133862, predicate)	ACCU-CHEK Aviva Connect System (new device)
Test Principle	Amperometric Detection	Same
Enzyme	Mut. Q-GDH	Same
Sample Hematocrit	10 to 65%	Same
Maximum Altitude	10,000 feet	Same
Measuring Range	20 – 600 mg/dL	Same
Sample Volume	0.6 µL	Same
Test Time	5 seconds	Same
Operating Temperature and Relative Humidity	(57 to 100°F) 10 to 80% r.h.	Same
Precision	For response targets < 75 mg/dL, the SD is ≤ 5.0 mg/dL, and for response targets ≥ 75 mg/dL, the CV is ≤ 5.0%.	Same
Closed and Open Vial Shelf Life Stability	18 months	Same
Double Dosing	No	Same
Control Solutions	Aqueous, 2 levels, uses ACCU-CHEK Aviva Control Solutions	Same
Primary Packaging	Standard flip top vial	Same
Limitations of Procedure	Galactose >15 mg/dL will cause overestimation of blood glucose results.	Same
	Lipemic Samples >1800 mg/dL	Same
	Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.	Same
	If peripheral circulation is impaired, collection of fresh capillary whole blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure, NYHA Class IV, or peripheral arterial occlusive disease.	Same

Intended Use

The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Aviva Connect Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Connect Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The single-patient use ACCU-CHEK Aviva Connect Blood Glucose Monitoring System will consist of:

Meter: ACCU-CHEK Aviva Connect Meter
Test Strip: ACCU-CHEK Aviva Plus Test Strip
Controls: ACCU-CHEK Aviva Control Solutions

**Substantial
Equivalence**

The ACCU-CHEK Aviva Connect system is substantially equivalent to the ACCU-CHEK Aviva Plus System (k133862).

**Data
demonstrating
substantial
equivalence**

Performance testing on the ACCU-CHEK Aviva Connect System demonstrated that the device meets the performance requirements for its intended use. The data demonstrates that the ACCU-CHEK Aviva Connect System is substantially equivalent to the predicate device.
